

REMARKS

This Application has been carefully reviewed in light of the Final Office Action mailed November 30, 2005. At the time of the Final Office Action, Claims 1-17 were pending in this Application. Claims 1-17 were rejected. Claims 1, 6, 11, 12 and 17 have been amended to further define various features of Applicants' invention. Claims 2, 7, 15 and 16 have been cancelled without prejudice or disclaimer. Applicants respectfully request reconsideration and favorable action in this case.

Rejections under 35 U.S.C. § 102

Claims 15 and 16 were rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,571,418 issued to Patrice A. Lee et al. ("Lee"). Applicants respectfully traverse and submit the cited art does not teach all of the elements of the claimed embodiments of Applicants' invention.

Claims 15 and 16 have been cancelled without prejudice or disclaimer to expedite allowance of the present application.

Claims 1, 2, 5-7, 10 and 12-17 were rejected by the Examiner under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,736,972 issued to James R. Matson ("Matson"). Applicants respectfully traverse and submit the cited art does not teach all of the elements of the claimed embodiments of Applicants' invention.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1997). Furthermore, "the identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Applicants respectfully submit that the cited art as anticipatory by the Examiner cannot anticipate the rejected Claims, because the cited art does not show all the elements of the present Claims.

Applicants respectfully submit that Matson does not show or teach the use of a plasma colloid replacement fluid as defined in amended Claim 1. Matson teaches the use of a

therapeutic agent which may be a pharmaceutical agent, activated protein C, other types of protein C and/or a biological agent. Several examples of pharmaceutical agents are provided. See Col. 14 line 59 through Col. 15 line 26 of Matson. Albumin is not a therapeutic agent as taught by Matson. Albumin is a class of simple water soluble proteins.

Claim 1 as amended also calls for various features of Applicants' invention which are neither shown nor taught by Matson including, but not limited to, "... sufficient clean albumin molecules to maintain adequate plasma oncotic pressure during the very large pore hemofiltration." Applicants request withdrawal of all rejections and allowance of Claim 1 as amended.

Claim 2 has been cancelled without prejudice or disclaimer.

Claim 5 which is dependent from amended Claim 1 further calls for "... the receptor molecules which are not contaminated corresponding with a plurality of receptor molecules contaminated with more than one inflammatory mediator removed from the patient's blood." Applicants respectfully submit that Matson does not show or teach a plasma colloid replacement fluid as defined in amended Claim 1 in combination with receptor molecules as defined in dependent Claim 5. Applicants request withdrawal of all rejections and allowance of Claims 3, 4 and 5.

Claim 6 as amended calls for various features of Applicants' invention including, but not limited to, a plasma colloid replacement fluid comprising "... a pharmaceutical grade balanced salt solution ... with sufficient clean albumin to maintain adequate plasma oncotic pressure during the very large pore hemofiltration.

Applicants request withdrawal of all rejections and allowance of Claim 6 as amended.

Claim 7 has been cancelled without prejudice or disclaimer.

Claims 8, 9 and 10 are dependent from Claim 6. Since Claim 6 as amended is now deemed allowable, Claims 8, 9 and 10 are allowable.

Applicants further note that Matson does not show or teach a plasma colloid replacement fluid as defined in Claim 6 having a concentration of albumin as defined in Claim 8 or Claim 9. Matson does not show or teach a plasma colloid replacement fluid as defined in amended Claim 6 having a plurality of clean target receptor molecules corresponding with a plurality of target receptor molecules contaminated with more than one

toxic removed from the patient's blood as called for in Claim 10. Applicants request withdrawal of all rejections and allowance of Claims 8, 9 and 10 as amended.

Claim 12 as amended calls for various features of Applicants' invention including, but not limited to, "... a blood filter having an effective molecular weight cutoff . . . greater than 150,000 Daltons . . . less than approximately 5,000,000 Daltons to avoid removal of significant amounts of immunoglobulin to prevent increasing the risk of opportunistic infection . . . a source for infusing clean albumin and clean target receptor molecules into the filtered blood stream. Applicants respectfully submit that Matson does not show or teach a blood filter having molecular weight cutoffs as defined in amended Claim 12 along with a source of infusing clean albumin and clean target receptor molecules into the filtered blood stream as further defined in amended Claim 12. Applicants request withdrawal of all rejections and allowance of Claim 12 as amended.

Claims 13 and 14 are dependent from Claim 12. Applicants request withdrawal of all rejections and allowance of Claims 12, 13 and 14 as amended.

Claims 15 and 16 have been cancelled without prejudice or disclaimer.

Claim 17 has been amended to call for various features of Applicants' invention including, but not limited to, "an extracorporeal blood circuit . . . the blood filter having an effective weight cutoff greater than 150,000 Daltons to sieve more than a nominal amount of the target molecules and the target complex molecules . . . the effective molecular weight cutoff of the blood filter less than approximately 5,000,000 Daltons to avoid removal of undesired amounts of immunoglobulins and similar large molecules . . . the replacement fluid providing sufficient clean albumin to maintain adequate plasma oncotic pressure." Applicants respectfully submit that Matson does not show or teach an extracorporeal blood circuit having a blood filter with molecular weight cutoffs as defined in amended Claim 17 in combination with the replacement fluid as defined in amended Claim 17. Applicants request withdrawal of all rejections and allowance of Claim 17 as amended.

Claims 1-10 were rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,900,720 issued to Ronald Kotischke ("Kotischke"), U.S. Patent No. 6,905,688 issued to Craig A. Rosen et al. ("Rosen et al.") and U.S. Patent No. 6,667,299 issued to Clarence Nathaniel Ahlem et al. ("Ahlem et al."). Applicants

respectfully traverse and submit that the cited art does not show or teach all of the features of the claimed embodiments of Applicants' invention.

Kotischke is related to therapeutic plasmapheresis and replacing a patient's plasma with a substitute medium. Kotischke does not show or teach a plasma colloid replacement fluid as defined in amended Claim 1. For example, Kotischke does not show or teach "... a pharmaceutical grade balanced salt solution having clean receptor molecules... which correspond with the receptor molecules... removed from the patient's blood during the very large pore hemofiltration..." Kotischke does not show or teach "a plasma colloid replacement fluid for replacing... contaminated target receptor molecules... removed from a patient's blood during very large pore hemofiltration..." as further defined in amended Claim 1.

Rosen et al. is generally related to therapeutic proteins fused to albumin or fragments or variants of albumin. Such therapeutic proteins may have use as "a therapeutic agent" such as described in Matson. Applicants' attorney has not found any suggestions or teachings in Rosen et al. related to a plasma colloid replacement fluid as further defined in amended Claims 1 and 6.

Ahlem et al. is generally related to methods to make and use steroids useful for a number of therapeutic and nontherapeutic applications, including use as immune modulators. Such steroids may have use as "a therapeutic agent" such as described in Matson. Applicants' attorney has not found any suggestions or teachings in Ahlem et al. related to a plasma colloid replacement fluid as further defined in amended Claims 1 and 6.

Claim 1 has been amended to call for various features of Applicants' invention including, but not limited to, "a plasma colloid replacement fluid for replacing receptor molecules... removed from a patient's blood during very large pore hemofiltration... a pharmaceutical grade balanced salt solution having... clean receptor molecules selected from the group consisting of albumin and clean carrier molecules... sufficient clean albumin molecules to maintain adequate plasma oncotic pressure during the very large pore hemofiltration."

Applicants respectfully submit that Kotischke, Rosen et al. and Ahlem et al. neither show nor teach any type of plasma colloid replacement fluid as defined in amended Claim 1. Applicants request withdrawal of all rejections and allowance of Claim 1 as amended.

Claims 3, 4 and 5 are dependent from Claim 1. Since Claim 1 as amended is now deemed allowable, Claims 3, 4 and 5 are allowable.

Applicants note that Kotischke, Rosen et al. and Ahlem et al. do not show or teach a plasma colloid replacement fluid as defined in amended Claim 1 having a concentration of albumin as defined in Claims 3 and 4.

Applicants note that Kotischke, Rosen et al. and Ahlem et al. do not show or teach a plasma colloid replacement fluid as defined in amended Claim 1 in combination with receptor molecules which are not contaminated corresponding with a plurality of receptor molecules contaminated with more than one inflammatory mediator removed from the patient's blood as called for in Claim 5.

Applicants request withdrawal of all rejections and allowance of Claims 3, 4 and 5 as amended.

Claim 6 has been amended to call for various features of Applicants' invention including, but not limited to, "a plasma colloid replacement fluid for replacing target receptor molecules . . . after the contaminated target receptor molecules have been removed from a patient's blood during very large pore hemofiltration . . . a pharmaceutical grade balanced salt solution having clean target receptor molecules corresponding with the contaminated target receptor molecules which have been removed from the patient's blood during the very large pore hemofiltration . . . with sufficient clean albumin to maintain adequate plasma oncotic pressure during the very large pore hemofiltration."

Applicants respectfully submit that Kotischke, Rosen et al. and Ahlem et al. neither show nor teach any type of plasma colloid replacement fluid as defined in amended Claim 6. Applicants request withdrawal of all rejections and allowance of Claim 6 as amended.

Claims 8, 9 and 10 are dependent from Claim 6. Since Claim 6 as amended is now deemed allowable, Claims 8, 9 and 10 are allowable.

Applicants note that Kotischke, Rosen et al. and Ahlem et al. do not show or teach a plasma colloid replacement fluid as defined in amended Claim 6 having a concentration of albumin as defined in Claims 8 and 9.

Applicants note that Kotischke, Rosen et al. and Ahlem et al. do not show or teach a plasma colloid replacement fluid as defined in amended Claim 6 in combination with receptor molecules which are not contaminated corresponding with a plurality of receptor molecules contaminated with more than one inflammatory mediator removed from the patient's blood as called for in Claim 10.

Applicants request withdrawal of all rejections and allowance of Claims 8, 9 and 10 as amended.

Rejections under 35 U.S.C. § 103

Claims 3, 4, 8, 9 and 11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matson in view of any one of Kotischke, Ahlem or Rosen. Applicants respectfully traverse and submit the cited art combinations, even if proper, which Applicants do not concede, does not render the claimed embodiment of the invention obvious.

In order to establish a *prima facie* case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Furthermore, according to § 2143 of the Manual of Patent Examining Procedure, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Claims 3 and 4 are dependent from amended Claim 1. Since Claim 1 as amended is now deemed allowable, Claims 3 and 4 are allowable. Applicants request withdrawal of all rejections and allowance of Claims 3 and 4.

Claims 8 and 9 are dependent from Claim 6. Since Claim 6 as amended is now deemed allowable, Claims 8 and 9 are allowable. Applicants request withdrawal of all rejections and allowance of Claims 8 and 9.

Claim 11 has been further amended to call for various features of Applicants' invention which are neither shown nor taught by Kotischke, Ahlem et al. and/or Rosen et al. including, but not limited to, "a plasma colloid replacement fluid kit for attachment to an extracorporeal blood circuit during very large pore hemofiltration . . . a plasma colloid replacement fluid and a reservoir . . . fluid formed in part by a pharmaceutical grade balanced salt solution . . . with a concentration of clean albumin at least sufficient to maintain a prescribed albumin concentration in the patient's circulatory system . . . other clean target receptor molecules operable to bind target molecules thereto for removal during the very large pore hemofiltration." Applicants request withdrawal of all rejections and allowance of Claim 11 as amended.

Request For Continued Examination

Applicants respectfully submit herewith a Request for Continued Examination (RCE) Transmittal, and a check in the amount of \$395.00 for the required filing fee. Applicants believe there are no additional fees due, however, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

Petition For Extension Of Time

Applicants respectfully submit herewith a Petition for Two-Month Extension of Time, along with a check in the amount of \$225.00 for the required filing fee.

CONCLUSION

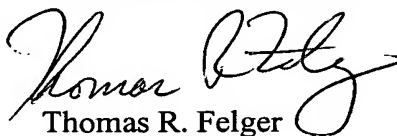
Applicants have now made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicants respectfully request reconsideration of Claims 1, 3-6, 8-14 and 17 as amended.

Applicants enclose a check for \$395.00 for the Request for Continued Examination. Applicants and enclose a check for \$225.00 for the Petition for a Two Month Extension of Time.

Applicants believe there are no additional fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicants' attorney at 512.322.2599.

Respectfully submitted,
BAKER BOTTS L.L.P.
Attorney for Applicants


Thomas R. Felger
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Date: 27 APR 2006

SEND CORRESPONDENCE TO:

BAKER BOTTS L.L.P.

CUSTOMER ACCOUNT NO. **31625**

512.322.2599

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- Enclosures:
1. Information Disclosure Statement and PTO Form 1449.
 2. Request for Continued Examination (RCE) and check in the amount of \$395.00.
 3. Petition for Two Month Extension of Time and a check in the amount of \$225.00.